

**ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES  
VACCINES FOR CHILDREN PROGRAM**

**HEPATITIS B**

**VACCINES TO PREVENT HEPATITIS B**

The purpose of this resolution is to revise the previous resolution to incorporate the use of a pentavalent vaccine: diphtheria and tetanus toxoids, acellular pertussis, hepatitis B, and polio vaccines and to clarify other use.

VFC resolution 10/01-2 is repealed and replaced by the following:

***Eligible Groups***

All previously unvaccinated children and adolescents from birth through 18 years.\*

*\*PEDIARIX™ is indicated for children  $\geq 6$  weeks of age and  $< 7$  years of age; COMVAX® is indicated for children  $\geq 6$  weeks of age; Twinrix® is only indicated for persons 18 years and older, and only children 18 years of age are eligible for Twinrix® through the VFC program.*

**Eligible Groups for Post-Exposure Immunoprophylaxis**

1. Infants of HBsAg-positive mothers:  
Infants born to mothers who are HBsAg-positive should receive appropriate doses of hepatitis B vaccine and hepatitis B immune globulin (HBIG) (0.5 ml) within 12 hours of birth and should complete the hepatitis B vaccine series according to the recommended schedule.
2. Persons whose sexual partners have acute hepatitis B:  
All previously unvaccinated sexual partners of persons with acute hepatitis B virus infection should receive the hepatitis B vaccine series and single dose of HBIG (0.06 ml/kg) if HBIG can be started within 14 days of the last sexual contact. The recommended schedule for hepatitis B vaccination of these persons is: 0, 1, 6 months; 0, 1, 4 months; or 0, 2, 4 months.
3. Persons with percutaneous or mucosal exposure to blood that contains (or might contain) HBsAg:  
For unvaccinated persons who have percutaneous or mucosal exposure to blood, the hepatitis B vaccine series should be initiated. If the source of exposure is HBsAg-positive, HBIG (0.06 ml/kg) should also be administered within 7 days of exposure.
4. Unvaccinated infants whose primary caregiver has acute hepatitis B:  
Infants whose primary caregiver has acute hepatitis B should receive a single dose of HBIG (0.5 ml) and complete the 3-dose hepatitis B vaccine series according to the recommended schedule.

**The routine recommended schedule for hepatitis B vaccination for infants born to Hepatitis B surface antigen (HBsAg) negative mothers is:**

**Vaccination Schedule Options**

	<b>Option 1*</b>			<b>Option 2</b>		
<b>Dose</b>	<b>Single antigen<sup>†</sup></b>	<b>Single antigen<sup>†</sup> / PEDIARIX™</b>	<b>Single antigen<sup>†</sup> / COMVAX®</b>	<b>Single antigen<sup>†</sup></b>	<b>PEDIARIX™</b>	<b>COMVAX®</b>
1	Birth	Birth (single antigen) <sup>‡</sup>	Birth (single antigen) <sup>‡</sup>	4-8 weeks	8 weeks	8 weeks
2	8 weeks	8 weeks	8 weeks	16 weeks	16 weeks	16 weeks
3	6 months	16 weeks	16 weeks	6-18 months	6 months	12-15 months
4		6 months	12-15 months	NA	NA	NA

\*Option 1 is preferred

<sup>†</sup>Single antigen vaccine: ENGERIX-B® or RECOMBIVAX®

<sup>‡</sup> Only a single antigen hepatitis B vaccine can be given at birth

### **COMBINATION VACCINES**

After single antigen hepatitis B vaccine is given at birth, an additional 3 doses of a hepatitis B containing combination vaccine can be given to complete the series starting after 6 weeks of age if the infant is also scheduled to receive the other components of the combination vaccine, and there are no contraindications to any of the components.

COMVAX®: The combination hepatitis B and *Haemophilus influenzae* type b (Hib) vaccine (COMVAX®)♦ is licensed for use at 2, 4, and 12-15 months of age. COMVAX® is not approved for hepatitis B vaccine doses at birth or at one month of age, and can only be given to infants 6 weeks of age or older. This vaccine may be used when administration of any component of this combination vaccine is indicated and if no components are contraindicated.

PEDIARIX™: The DTaP-Hepatitis B-Inactivated Poliovirus Vaccine combination (PEDIARIX™)♦ is licensed for use at 2, 4, and 6 months of age. PEDIARIX™ is not approved for the hepatitis B vaccine dose at birth and cannot be given to infants < 6 weeks of age or individuals ≥7 years of age. This vaccine may be used when administration of any component of this combination vaccine is indicated for the primary series and if no components are contraindicated. The 3<sup>rd</sup> dose of PEDIARIX™ should be given at least 16 weeks after the first dose, preferably at 6 months of age but not before 24 weeks of age.

**PRETERM INFANTS:** Preterm infants of HBsAg negative mothers who weigh less than 2kg at birth should receive the first dose of hepatitis B vaccine series when the infant is ≥1 month of age, including infants who remain hospitalized. Preterm infants discharged from the hospital before chronological age 1 month can also be administered hepatitis B vaccine at discharge, if they are medically stable and have gained weight consistently.

♦ Use of brand names is not meant to preclude the use of other comparable licensed hepatitis B-Hib or DTaP-Hepatitis B-IPV combination vaccines.

**Recommended schedule of hepatitis B immunoprophylaxis to prevent perinatal transmission of hepatitis B virus infection:**

Infant born to mother known to be HBsAg-positive

**Vaccination Schedule Options**

<b>Dose</b>	<b>Single antigen vaccine*</b>	<b>PEDIARIX™</b>	<b>COMVAX®</b>
1	Birth	Birth (single antigen) <sup>‡</sup>	Birth (single antigen) <sup>‡</sup>
2	4 weeks	6-8 weeks	6-8 weeks
3	6 months	16 weeks	16 weeks
4	NA	6 months	12-15 months

\* Single antigen vaccine: ENGERIX-B® or RECOMBIVAX®

‡ Only a single antigen hepatitis B vaccine is given at birth. Hepatitis B immune globulin (HBIG) should also be given to all infants within 12 hours of birth – 0.5 ml administered intramuscularly at a site different from that used for vaccine.

**COMBINATION VACCINES**

After single antigen hepatitis B vaccine is given at birth, an additional 3 doses of a hepatitis B containing combination vaccine can be given to complete the series starting after 6 weeks of age if the infant is also scheduled to receive the other components of the combination vaccine, and there are no contraindications to any of the components.

COMVAX®: The combination hepatitis B and *Haemophilus influenzae* type b (Hib) vaccine (COMVAX®)<sup>♦</sup> is licensed for use at 2, 4, and 12-15 months of age.

COMVAX® is not approved for hepatitis B vaccine doses at birth or at one month of age, and can only be given to infants 6 weeks of age or older. This vaccine may be used when administration of any component of this combination vaccine is indicated and if no components are contraindicated.

PEDIARIX™: The DTaP-Hepatitis B-Inactivated Poliovirus Vaccine combination (PEDIARIX™)<sup>♦</sup> is licensed for use at 2, 4, and 6 months of age. PEDIARIX™ is not approved for the hepatitis B vaccine dose at birth and cannot be given to infants <6 weeks of age or individuals ≥7 years of age. This vaccine may be used when administration of any component of this combination vaccine is indicated for the primary series and if no components are contraindicated. The 3<sup>rd</sup> dose of PEDIARIX™ should be given at least 16 weeks after the first dose, preferably at 6 months of age but not before 24 weeks of age.

**PRETERM INFANTS:** For preterm infants who weigh < 2 kg at birth, the initial vaccine dose should not be counted as part of the vaccine series, and three doses of vaccine should be administered beginning when the infant is ≥1 month of age.

♦ Use of brand names is not meant to preclude the use of other comparable licensed hepatitis B-Hib or DTaP-Hepatitis B-IPV combination vaccines.

**Recommended schedule of hepatitis B immunoprophylaxis to prevent perinatal transmission of hepatitis B virus infection:**

Infant born to mother with an unknown HBsAg status

**Vaccination Schedule Options**

<b>Dose</b>	<b>Single antigen vaccine*</b>	<b>PEDIARIX™</b>	<b>COMVAX®</b>
1	Birth‡	Birth (single antigen)‡	Birth (single antigen)‡
2	4 weeks	6-8 weeks	6-8 weeks
3	26 weeks	16 weeks	16 weeks
4	NA	6 months	12-15 months

\* Single antigen vaccine: ENGERIX-B® or RECOMBIVAX®

‡ Only a single antigen hepatitis B vaccine is given at birth. Hepatitis B immune globulin (HBIG) should also be given to all infants within 12 hours of birth – 0.5 ml administered intramuscularly at a site different from that used for vaccine.

**COMBINATION VACCINES**

After single antigen hepatitis B vaccine is given at birth, an additional 3 doses of a hepatitis B containing combination vaccine can be given to complete the series starting after 6 weeks of age if the infant is also scheduled to receive the other components of the combination vaccine, and there are no contraindications to any of the components.

COMVAX®: The combination hepatitis B and *Haemophilus influenzae* type b (Hib) vaccine (COMVAX®)♦ is licensed for use at 2, 4, and 12-15 months of age.

COMVAX® is not approved for hepatitis B vaccine doses at birth or at one month of age, and can only be given to infants 6 weeks of age or older. This vaccine may be used when administration of any component of this combination vaccine is indicated and if no components are contraindicated.

PEDIARIX™: The DTaP-Hepatitis B-Inactivated Poliovirus Vaccine combination (PEDIARIX™)♦ is licensed for use at 2, 4, and 6 months of age. PEDIARIX™ is not approved for the hepatitis B vaccine dose at birth and cannot be given to infants <6 weeks of age or individuals ≥7 years of age. This vaccine may be used when administration of any component of this combination vaccine is indicated for the primary series and if no components are contraindicated. The 3<sup>rd</sup> dose of PEDIARIX™ should be given at least 16 weeks after the first dose, preferably at 6 months of age but not before 24 weeks of age.

**PRETERM INFANTS:** For preterm infants who weigh < 2 kg at birth, the initial vaccine dose should not be counted as part of the vaccine series, and three doses of vaccine should be administered beginning when the infant is ≥1 month of age.

♦Use of brand names is not meant to preclude the use of other comparable licensed hepatitis B-Hib or DTaP-Hepatitis B-IPV combination vaccines.

## Catch-Up Vaccination

The ACIP recommends catch-up vaccination of previously unvaccinated children and adolescents less than 19 years of age. The recommended dosing schedules for unvaccinated children and adolescents are:

Option 1: 3 dose pediatric/adolescent formulation for children < 19 years of age:

<u>Dose</u>	<u>Usual Interval</u>
Hep B-1	-----
Hep B-2	1 month
Hep B-3	4-6 months

Option 2: 2 dose adult formulation (RECOMBIVAX HB<sup>®</sup>, Merck & Co.) ♦ for children 11-15 years of age:

<u>Dose</u>	<u>Usual Interval</u>
Hep B-1	-----
Hep B-2	4-6 months

Option 3: 3 dose adult formulation (Twinrix<sup>®</sup>, GlaxoSmithKline) ♦ for persons 18 years of age:

<u>Dose</u>	<u>Usual Interval</u>
Hep B-1	-----
Hep B-2	1 month
Hep B-3	5 months

**Minimum Age and Dosage Intervals**

Vaccine	Minimum age at first dose	Minimum interval from dose 1 to 2	Minimum interval from dose 2 to 3 (when applicable)	Minimum interval from dose 1 to 3 (when applicable)
<b>Infants</b>				
Hepatitis B (3 dose schedule with pediatric single antigen formulation)	Birth	4 weeks	8 weeks	16 weeks ♦
COMVAX <sup>®</sup> *	6 weeks	4 weeks	8 weeks‡	N/A
PEDIARIX <sup>TM</sup> *	6 weeks	4 weeks	8 weeks	16 weeks ♦
<b>Adolescents (11-18 years)</b>				
Hepatitis B (3 dose schedule with pediatric single antigen formulation)	N/A	4 weeks	8 weeks	16 weeks ♦
Hepatitis B (2 dose schedule with adult formulation for children 11-15 years of age)	11 years	16 weeks	N/A	N/A
Hepatitis B (3 dose schedule as combined hepatitis A/hepatitis B vaccine, Twinrix <sup>®</sup> )	18 years	4 weeks	5 months	6 months

♦ The third dose of hepatitis B vaccine dose should not be given to infants before 24 weeks of age.

\*Three doses of combination vaccines may be given to complete the hepatitis B vaccine series after the preferred dose at birth. Combination vaccines cannot be given before 6 weeks of age. When used following a birth dose, dose number refers to the dose of combination vaccine.

‡ If Comvax is given for the first two doses of Hib Vaccine, the third dose (booster) should be given at 12 –15 months of age.

## Contraindications and Precautions

The following conditions are contraindications to the administration of hepatitis B vaccine:

1. **Anaphylactic reaction to a previous dose of hepatitis B vaccine.**  
Further vaccination with hepatitis B and/or hepatitis B/Hib vaccine is contraindicated in persons with a history of anaphylaxis (severe allergic reaction) after a previous dose of hepatitis B and/or hepatitis B/Hib vaccine.
2. **Administration of COMVAX<sup>®</sup> vaccine or other hepatitis B/Hib vaccines to infants younger than 6 weeks of age.**  
Combined hepatitis B/Hib vaccine must not be administered to infants younger than 6 weeks of age because of potential suppression of the immune response to the Hib component of the vaccine.
3. **Administration of PEDIARIX<sup>™</sup> vaccine to infants younger than 6 weeks of age or individuals  $\geq 7$  years of age.**  
The DTaP-Hepatitis B-IPV combination vaccine is not approved for use in infants  $< 6$  weeks of age or individuals  $\geq 7$  years of age.
4. **Administration of Twinrix<sup>®</sup> vaccine to persons younger than 18 years of age.**  
Combined hepatitis A/hepatitis B vaccine is not licensed for use in persons younger than 18 years of age.
5. **Moderate or severe acute illnesses with or without fever.**  
The following conditions are contraindications to the administration of hepatitis B immune globulin (HBIG):

1. **Anaphylactic reaction to a previous dose of any immune globulin preparation.**
2. **Serum immunoglobulin A deficiency.**

***The following conditions are contraindications to the administration of DTaP-HepB-IPV combination vaccine:***

1. The DTaP-HepB-IPV combination (PEDIARIX<sup>™</sup>), is not indicated for use in infants  $\leq 6$  weeks or  $> 7$  years of age.
2. **An immediate anaphylactic reaction.**  
Further vaccination with DTaP-Hep B-IPV (PEDIARIX<sup>™</sup>) or any of its components (DTaP, Hep B, or IPV) vaccines should be deferred because of uncertainty as to which component of the vaccine might be responsible. However, because of the importance of tetanus vaccination, persons who experience anaphylactic reactions maybe referred to an allergist for evaluation and (if specific allergy can be demonstrated) desensitized to tetanus toxoid.
3. **Encephalopathy not attributed to another identifiable cause.**  
An acute, severe central nervous system disorder occurring within 7 days after vaccination and generally consisting of major alterations in consciousness,

unresponsiveness, or generalized or focal seizures that persist more than a few hours, without recovery within 24 hours. In such cases, component vaccines must be administered separately and DT vaccine instead of DTaP should be administered for the remaining doses in the vaccination schedule to ensure protection against diphtheria and tetanus.

**4. Acute, moderate or severe illnesses with or without fever.**

***The following conditions are precautions to receipt of DTaP-Hep B-IPV combination vaccine:***

*If any of the following events occurs within the specified period after administration of DTaP-Hep B-IPV, vaccine providers and parents should evaluate the risks and benefits of administering subsequent doses of a pertussis-containing vaccine:*

1. Temperature of  $\geq 105^{\circ}\text{F}$  ( $\geq 40.5^{\circ}\text{C}$ ) within 48 hours, not attributable to another identifiable cause.
2. Collapse or shock-like state (hypotonic hyporesponsive episode) within 48 hours.
3. Persistent crying lasting  $\geq 3$  hours, occurring within 48 hours.
4. Convulsions with or without fever, occurring within 3 days.

**Adopted and Effective: February 26, 2003**

Note: Vaccines approved by the ACIP for inclusion in the VFC program are not available for use in the program until after the CDC has established a contract for the purchase of the vaccines.